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10/756,765	01/14/2004	Per Egnelov	030481-0212	1510
22428	7590	02/14/2006	EXAMINER	
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			MALLARI, PATRICIA C	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/756,765

Applicant(s)

EGNELOV ET AL.

Examiner

Patricia C. Mallari

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-16 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9,15 is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-14,16,20 and 23 is/are rejected.
- 7) ☒ Claim(s) 21 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This is a non-final Office action. The allowability of claims 10-14 and 16 has been regrettably withdrawn, and rejections of those claims based on US Patent No. 6,193,670 to Van Tassel, US Patent No. 3,730,168 to McWhorter, and US Patent No. 6,485,428 to Enk are presented below.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-7, 13, 14, 16, 20, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,193,670 to Van Tassel et al. Van Tassel teaches an indicator device for visually indicating a blood pressure inside a blood vessel, comprising a body comprising a passage (lumen extending from seal 30 to ports 52, 54, see fig. 3 of Van Tassel) passing through the body, the body further comprising a duct 32 extending in the body and having a hemostatically sealed blood accommodating chamber 44. An insertion tube 12 comprises a distal end portion 17 adapted to be positioned inside the blood vessel and comprises a fluid communication pathway 22 between a liquid inlet opening 52, 54 near a distal end 16 of the insertion tube 12 and the duct 32. A window 46 comprises an at least semi-transparent section configured to enable visual observation of blood entering into the duct via the inlet opening when the inlet opening is located inside the blood vessel (figs. 1-3; col. 5, lines 14-63; col. 6, lines

11-26 of Van Tassel). An elongated member 88 is further included, wherein the passage and the fluid communication pathway are adapted to permit a member to be threaded in a substantially straight path therethrough between a distal and proximal end of the indicator device (figs. 7 and 8; col. 5, lines 27-32; col. 6, line 55-col. 7, line 7 of Van Tassel.)

Regarding claim 3, the duct 32 opens into the chamber 44 via an aperture having a spill-over edge 42, the aperture being located at a level above a bottom surface of the blood accommodating chamber, whereby return flow of blood back into the duct is prevented (figs. 1 & 2 of Van Tassel).

Regarding claim 4, the blood-accommodating chamber 44 is located in the body and wherein the body further comprises the insertion tube 12 extending distally of the body (figs. 1-3 of Van Tassel).

Regarding claim 5, the inlet opening 50, 52, 54 is located on a side of the insertion tube 12 (figs. 1-3 of Van Tassel).

Regarding claims 6 and 7, the duct 32 extends vertically or horizontally to an aperture opening into the blood-accommodating chamber 44 (fig. 1 of Van Tassel), wherein the determination of whether the duct extends vertically or horizontally depends on the orientation of the device. The device of Van Tassel can be held or placed such that the duct can be considered to extend vertically or horizontally.

Regarding claim 13, Van Tassel also describes an embodiment of an indicator device for visually indicating blood pressure in a blood vessel having substantially

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similar features as the embodiment of figures 1-3 except that the duct is helically shaped (Figs. 10-12; col. 8, lines 10-29 of Van Tassel).

Regarding claims 14 and 16, the blood-accommodating chamber 44 and the duct 32 are dimensioned such that a counter-pressure therein when blood enters will cause a blood meniscus at a lowest possible systolic pressure to be located within the window 46 (figs. 1-3; col. 6, lines 26-30 of Van Tassel). With further regard to claim 16, since the configuration of the meniscus is formed based on the position of the device with respect to gravity, the configuration of the meniscus with regard to the direction of flow in the duct is regarded as "intended use" language, which cannot be relied upon to define over the prior art of Van Tassel, since the prior art reference teaches all of the claimed elements and their recited relationships. The device of Van Tassel can be positioned such that the direction of flow in the duct is perpendicular to the meniscus.

Regarding claim 20, the indicator device is provided, the distal end portion 16 is positioned inside the blood vessel and the blood pressure is indicated (figs. 1, 5-8; col. 6, lines 11-29; col. 6, line 56-col., 7, line 25 of Van Tassel).

Regarding claim 23, the elongated member comprises a guide wire 88 (col. 6, lines 59-63 of Van Tassel).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Tassel, as applied to claims 1, 3-7, 13, 14, 16, and 20 above, and further in view of US Patent No. 6,485,428 to Enk. Van Tassel fails to teach the duct widening in the direction towards the blood-accommodating chamber.

However, Enk teaches an indicator device for visually indicating a pressure blood inside a blood vessel, wherein the duct extending in the body has a varying cross-section over its length such that it widens in the direction of the blood accommodating chamber (figs. 4, 5, and 10; col. 12, line 52-col. 13, line 12; col. 14, lines 3-19 of Enk). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a duct that widens in the direction towards the blood accommodating chamber rather than a duct of uniform diameter in the device of Van Tassel in order to permit accurate measurement of low pressure values at an upwardly large, open measuring scale (col. 5, lines 26-33; col. 12, lines 52-57; col. 14, lines 15-18 of Enk).

Regarding claim 11, the duct first becomes narrow and then widens in figures 4, 5, and 10 of Enk.

Regarding claim 12, the entirety of the duct appears to be transparent such that the duct itself is the window of the apparatus (col. 3, lines 40-45 of McWhorter). Therefore variation in cross-section of the duct would also occur over the length of the window.

### ***Response to Arguments***

In the arguments filed 6/28/05, the applicants stated (pp. 8& 9) that Van Tassel fails to teach that the passage and fluid communication pathway are adapted to permit a member to be threaded in a substantially straight path between a proximal end and a distal end of the indicator device, and further cite that Van Tassel has a closed off distal end 17, 86, or 140. However, claims 1 and 20 only recite that "the passage and the fluid communication pathway are adapted to permit the elongated member to be threaded in a substantially straight path there through between a distal end and a proximal end of the indicator device." The language of claims 1 and 20 fails to require that the structure of the device should allow the elongated member to be threaded through the entirety of the passage and fluid communication pathway such that the elongated member *extends past* the distal end of the device. As described above Van Tassel discloses an embodiment that explicitly shows an elongated member extending in a substantially straight path through the passage and the fluid communication pathway between a proximal end of the indicator device and a distal end of the device. Van Tassel, as described in more detail above, therefore meets the limitations of claims 1 and 20.

Applicant's arguments filed 12/1/05 with respect to claims 1, 3-8, and 20 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Allowable Subject Matter***

Claims 9 and 15 are allowed. The allowability of claims 9 and 15 was addressed in a previous Office action filed 4/20/05 and are reprinted below.

Claims 21 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 9, the prior art of record fails to teach or fairly suggest a blood pressure indicator device comprising a body comprising a duct wherein the sealed proximal end of the duct comprises a blood accommodating chamber, and wherein the duct becomes narrower in the direction towards the blood accommodating chamber, and in combination with all of the other limitations of the claim.

Regarding claim 15, the prior art of record fails to teach or fairly suggest a blood pressure indicator device comprising a blood accommodating chamber and duct dimensioned such that a counter-pressure therein, when blood enters, will cause a blood meniscus at a lowest possible systolic pressure to be located approximately at the spill-over edge.

Regarding claims 21 and 22, the prior art of record fails to teach or fairly suggest an indicator device for visually indicating a blood pressure inside of a blood vessel wherein the elongated member comprises a guide rod or a dilator, and in combination with all of the other limitations of the claims.

### ***Conclusion***




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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Patricia Mallari  
Patent Examiner  
Art Unit 3736

  
ROBERT L. MADER  
PRIMARY EXAMINER